REMARKS

FORMAL MATTERS:

Claims 29 and 41-46 are pending and stand rejected.

Claims 1-28 and 30-40 are cancelled.

Claims 41, 43, 45, and 61 are amended for further clarity. No new matter is added.

In view of the remarks set forth below, reconsideration of this application is respectfully requested.

REJECTION OF CLAIMS UNDER 35 U.S.C. §112, ¶2

Claims 41, 43 and 44-61 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the phrase: "wherein the G protein-coupled receptor .....*increases* an intracellular level of IP_3". In attempting to establish this rejection, the Examiner argues that the term "increases" is a relative term and, as such, one of skill in the art would not be reasonably apprised of the scope of the claim.

According to MPEP § 2173[1], the standard for meeting the requirement for definiteness set forth in 35 U.S.C. § 112, second paragraph, is an objective one that requires an analysis of the specification, the teachings of the prior art, and how the claim would be read by one of one of ordinary skill in the art. Per MPEP § 2173.02, the claims should *not* be analyzed for definiteness in a vacuum.

The Applicants submit that given the specification and the teachings of the prior art, one of skill in the art would have no trouble understanding what is meant by the phrase "wherein the G protein-coupled receptor .....*increases* an intracellular level of IP_3".

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[1] See, e.g., MPEP § 2173.02: "The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

Nevertheless, claims 41, 43, 45 and 61 are amended to recite "wherein the G protein-coupled receptor .....*increases* an intracellular level of IP_3 *when stimulated*".

The Applicants submit that this rejection has been adequately addressed by the foregoing discussion. Withdrawal of this rejection is respectfully requested.

Claim 44 is further rejected under 35 U.S.C. §112, second paragraph, as being indefinite for not reciting precise hybridization or wash conditions.

Claim 44 is directed to a composition amplifiable by PCR from human cDNA using specific primers. As would be recognized by one of skill in the art, the only products amplifiable from human cDNA which encode an endogenous human G protein-coupled receptor using the recited primers are endogenous human RUP35 cDNAs.

Given that the primers used amplify the coding sequence for a single gene, the metes and bounds of claim 44 should be readily apparent. Since no more is required to satisfy the requirement for definiteness of 35 U.S.C. § 112, second paragraph, this rejection should be withdrawn.

Withdrawal of this rejection is respectfully requested.

REJECTION UNDER §101

Claims 29 and 41-46 stand rejected under 35 U.S.C. § 101 as lacking patentable utility. The Applicants respectfully traverse this rejection.

In summary, the Applications submit that the instant specification asserts a role for hRUP35 in motor control.[2] This is not disputed. In the Office Action, the Examiner presents 33 pages of arguments that allegedly support the conclusion that hRUP35 has no patentable utility under §101. This conclusion, in a nutshell, is largely based on arguments that the asserted utility of hRUP35 in motor control is neither substantial, specific nor credible. The Applicants submit that the asserted utility of hRUP35 in motor control satisfies §101. Further, the asserted utility of

[2] See, e.g., page 19, lines 9-11 of the instant specification: "For example and not limitation, proteins located/expressed in areas of the thalamus [e.g., hRUP35] are associated with sensorimotor processing and arousal".

hRUP35 in motor control has since been confirmed by others.[3] As such, the Examiner's arguments are believed to be moot, and this rejection should be withdrawn.

The main point that Applicants wish to convey to the Examiner in this response is set forth above. To the extent that further discussion is deemed necessary, the Examiner is respectfully referred to the following.

The Utility Examination Guidelines state that Office personnel are to adhere to the following procedures when applying a rejection under 35 U.S.C. §101. Any rejection based on lack of utility should include a detailed explanation as to why the claimed invention has no specific and substantial credible utility.[4] Whenever possible, the Office should provide documentary evidence.[5] In the absence of documentary evidence, the Office must provide a prima facie showing that establishes that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the Applicants for the claimed invention. A prima facie showing must contain the following elements: (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record.[6] *A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.* Utility Examination Guidelines, *Federal Register* (Jan. 5, 2001) Vol. 66(4):1092-1099, emphasis added.

It is well established that "a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a

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[3] See, e.g., Torres *et al.*, Abstract 328 of the 2006 Keystone Symposium, who makes homozygous mice containing a knockout of the mouse homolog of hRUP35 and show that those mice have a motor deficit.
[4]Fed. Reg. Vol. 66 at page 1098, Section II-B, paragraph 3.
[5]Fed. Reg. Vol. 66 at page 1098, Section II-B, paragraph 3.
[6]Fed. Reg. Vol. 66 at page 1098, Section II-B, paragraph 3.

reason for the skilled in the art to question the objective truth of the statement of utility or its scope." *In re Langer* 183 USPQ 288, 297 (CCPA 1974) (emphasis in original).

In this case, the Applicants have asserted in the instant specification that hRUP35 (which is encoded by the claimed polynucleotides) is involved in motor control. Given this information, one of skill in the art would recognize that hRUP35 is useful in identifying compounds, e.g. agonists and inverse agonists, for the treatment of motor control symptoms in disorders and diseases of motor control.

Given that the asserted role of hRUP35 in motor control has been confirmed by Torres *et al., supra*, the Applicants submit that one of skill in the art would have no reason to question the objective truth of the Applicants' statement. This rejection should be withdrawn for this reason alone.

In the Office Action, the Examiner presents several lines of reasoning to counter the Applicants' assertion of utility.

In one line of reasoning, the Examiner argues that it is unreasonable to conclude that hRUP35 has a utility in motor control based on hRUP35's expression pattern. The Applicants submit, however that Sesens *et al,*[7] a post-filing publication, independently came to the same conclusion as the Applicants – namely that hRUP35 is involved in motor control – based on the expression pattern of the mouse homolog of hRUP35. As such, the Applicants submit the asserted utility of hRUP35 in motor control is reasonable. Further, since Torres *et al, supra,* confirmed the asserted utility of hRUP35 in motor control, the Examiner's argument lacks force and merit.

In another line of reasoning, the Examiner counters the Applicants' position by arguing, in summary, that the Applicants allegedly do not know the exact function or ligand of hRUP35, or the exact mechanism by which hRUP35 works. The Applicants submit, however that the utility requirement under §101 does not require that the ordinarily skilled artisan understand *why* the claimed subject matter is useful or the exact mechanism through which a receptor works.

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[7] See page 20, last sentence, where *Sesens* states "The presence of GPR139 in brain areas involved in motor control suggests a function as mediator in locomotor activity."

Instead, the skilled artisan need only be told that it is useful and how it can be used. Applicants have met those burdens.

It is well established that an understanding of the scientific theory or principle underlying an invention is *not* a requirement for patentability.[8] Thus, while the exact mechanism of action of hRUP35 might be an interesting topic for discussion, assertions regarding the mechanism of action of hRUP35 has no bearing on the patentability of the rejected claims.

Finally, in another line of reasoning, the Examiner argues that the specification does not link hRUP35 to any particular disease. In an attempt to support this argument, the Examiner lists a plethora of different disorders that range from erectile dysfunction to myoclonic seizure, and argues that one of skill in the art would not know with which disorder hRUP35 is associated. In response, the Applicants submit that the Examiner's requirement that hRUP35 be linked to a particular disorder is far beyond the requirements of §101, and indeed misses a key point that the Applicants have made.

The Applicants have asserted that hRUP35 is linked to motor control. Since motor control dysfunction can appear as a symptom of a number of different diseases, modulators of hRUP35 may be employed to modulate motor function in a number of different diseases.

The situation here is much akin to that of, for example, inflammation. While drugs that modulate inflammation (e.g., cortisone, a glucocorticoid steroid) are certainly useful, those drugs are not directly linked to treatment of any particular disease. Cortisone, for example, is used to treat inflammation in a number of disorders, including shoulder bursitis, arthritis, tennis elbow and carpal tunnel syndrome. The skilled artisan would readily appreciate that nucleic acid encoding the glucocorticoid receptor and screens to identify modulators of the glucocorticoid receptor are useful, despite the lack of direct link between the glucocorticoid receptor and a single, specific disorder.

It is understood that the points made by the Examiner in this Office Action, which largely relate to: a) whether it is reasonable to conclude that hRUP35 has a utility in motor control based

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[8] See, e.g., In re Gazave, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); In re Chilowsky, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956) and Philip Morris, Inc. v. Brown &

on hRUP35's expression pattern; b) the exact function, ligand and mechanism of action of hRUP35; and c) the link between hRUP35 and a single disease, are addressed above.

The Applicants prior arguments still stand and are incorporated herein but reiterated for the sake of brevity. In the event that the above arguments are found unpersuasive, the Applicants' prior arguments are hereby preserved for Appeal.

The Applicants respectfully submit that in view of the foregoing discussion, this rejection should be withdrawn. Withdrawal of this rejection is requested.

REJECTIONS UNDER §112, ¶1 (ENABLEMENT - UTILITY)

Claims 29 and 41-46 are rejected as not meeting the "how to use" part of the enablement requirement of 35 U.S.C. § 112, first paragraph.

The basis for this rejection is the Examiner's contention that the claims are not supported by a patentable utility.

As such, it is believed that this rejection has been adequately addressed in the discussion in the preceding section of this response.

In view of the discussion in the preceding section of this response, this rejection should be withdrawn.

REJECTIONS UNDER §112, ¶1 (ENABLEMENT - SCOPE)

Claims 44-61 are rejected as not meeting the enablement requirements of 35 U.S.C. § 112, first paragraph. The Applicants respectfully traverse this rejection.

The law regarding enablement of inventions is clear: "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."[9]

Williamson Tobacco Corp., 641 F. Supp. 1438, 1483 n.13, 231 USPQ 321, 355 n.13 (M.D. Ga. 1986).

[9] *United States v. Telectronics, Inc.*, 8 USPQ 2d 1217, 1233 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). See also *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).

The Examiner is respectfully reminded that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims (MPEP §2164.08) and the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled (MPEP §2164.08(b)). The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort that is normally required in the art (MPEP §2164.08(b)).

Claims 44-61 recite a composition amplifiable by PCR from human cDNA using specific primers.

Since PCR methods have been routine in molecular biology laboratories since the late 1980's, the Applicants submit that *making* the claimed subject matter requires no undue experimentation.

With regard to *using* the amplified subject matter, the Applicants submit that the only products amplifiable from human cDNA which encode an endogenous human G protein-coupled receptor using the recited primers are endogenous human RUP35 cDNAs. One of skill in the art would not expect great variation between the RUP35 cDNAs amplified by the recited primers and, as such, those molecules may be *used* without undue experimentation.

In view of the foregoing discussion, the Applicants submit that the claimed nucleic acids can be made *and* used without undue experimentation. Since this is all that is required by the enablement requirement of 35 U.S.C. § 112, first paragraph, this rejection should be withdrawn.

As best understood by the Applicants, the Examiner's concern appears to be that the specification does not provide an explicit structural and functional description of the variants of SEQ ID NO:15 that are amplifiable from human cDNA using the recited primers.

The Applicants note, however, that claiming subject matter in terms of a process by which the subject matter is obtainable is an accepted way of claiming a composition without providing an explicit physical description of the composition being claimed.[10] The Examiner's apparent requirement for an explicit description of the structural and functional characteristics of the variants of SEQ ID NO:15 that are obtainable by PCR of human cDNA is overly stringent.

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[10] See, e.g., MPEP § 2113.

The Applicants submit that this rejection has been adequately addressed in the foregoing discussion. Withdrawal of this rejection is respectfully requested.

REJECTIONS UNDER §112, ¶1 (WRITTEN DESCRIPTION)

Claims 44-61 are rejected as not meeting the written description requirements of 35 U.S.C. § 112, first paragraph. The Applicants respectfully traverse this rejection.

As best understood by the Applicants, this rejection is based on the Examiner's assertion that the nucleotide sequences of all of the nucleic acids encompassed by the claim are not explicitly described in the specification.

Claims 44-61 recite a composition amplifiable by PCR from human cDNA using specific primers. As such, claims 44-61 are so-called "product-by-process" claims.

Given that the rejected claims are product-by-process claims, the Examiner's apparent requirement for an explicit description of the structural and functional characteristics of each of the variants of SEQ ID NO:15 that are obtainable by PCR of human cDNA appears to be overly stringent.

Furthermore, the Applicants further note that the written description requirement of 35 U.S.C. §112, first paragraph, does not require a description of the complete structure of every species within a chemical genus, particularly when one of skill in the art would not expect substantial variation within those species.[11]

The only products amplifiable from human cDNA which encode an endogenous human G protein-coupled receptor using the recited primers are endogenous human RUP35 cDNAs. Given that the claims encompass only natural variants of human RUP35, the Applicants submit that the genus is adequately described by disclosure of a single species.

Evidence that one of skill in the art would not expect substantial variation within those species encompassed by the rejected claims is supported by, e.g., entries into the so called "GPCR

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[11] See, e.g., *Utter v. Higara* 845 F.2d 993, 998, 6 USPQ 1709, 1714 (Fed. Cir. 1998) ("A specification may, within the meaning of 35 U.S.C. §112, ¶1 contain a written description of a broadly claimed invention without describing all species the claim encompasses."). See also *Enzo Biochem*, 296 F.3d 1316, 63 USPQ2d 1602 (Fed. Cir. 1998) and Examples 9 and 13 of the "Synopsis of Application of Written Description Guidelines", as published to the world wide website of the U.S.P.T.O. on March 1st, 2000.

natural variants database" (see http://nava.liacs.nl/index.html) which lists the amino acid sequences of many GPCRs and their natural variants. According to this database, (see., e.g., the variation in the D(1A) dopamine receptor found at http://nava.liacs.nl/cgi-bin/result_page_general.py?acc=P21728, natural variants of a GPCR often have amino acid substitutions at a *single* position within the GPCR. Thus, the expected structural variation of human RUP35 molecules recited in the rejected claims is not substantial.

The Applicants submit that this rejection has been adequately addressed. Withdrawal of this rejection is respectfully requested.

The Applicants finally note that withdrawal of this rejection would be consistent with recent decisions by the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. The decisions are and *Ex parte Bandman* BAPI Appeal No. 2004-2319 (2004) and *Ex parte Sun* BAPI Appeal No. 2003-1993 (2003), among others. The genus claims that are the subject of in these decisions were supported by disclosure of a *single* representative species encompassed by the claims.

CONCLUSION

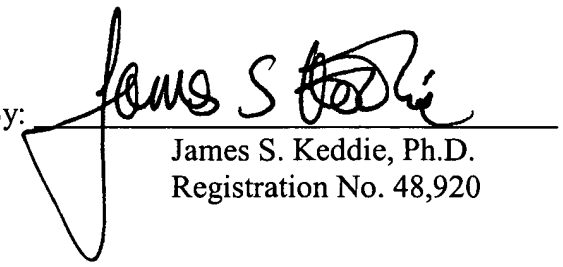
Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AREN-021CIP.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date: March 8, 2007

By: 

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